SEQ ID NO: 4, and a method of immunizing a mammal by administering a protein; (V) Claims 42, 50, and 54, drawn to a diagnostic method for determining group B streptococcal infection or colonization by detecting the *spb1* gene product; and (VI) Claims 43, 51, and 55, drawn to a diagnostic method for determining group B streptococcal infection or colonization by detecting the *spb2* gene product. The Examiner further designated claims 41, 44-49, 52, and 53 as linking claims that would be joined with either group V or group VI if elected.

The Applicants provisionally elect the invention of group I **with traverse,** believing that the requirement is in part improper under PCT rules 13.1 and 13.2 describing unity of invention, and believing that the requirement is fully improper under USPTO procedures and policies governing the examination of nationalized PCT cases having claims directed to nucleotide sequences. As a result, the Applicants respectfully request that this Requirement be reconsidered as provided in 37 C.F.R. 1.499, which states that review of restriction requirements made in national stage applications are subject to review as laid out in 37 C.F.R. §§1.143-1.144. *See, e.g.,* Manual of Patent Examining Procedure (hereinafter "MPEP") §1893.03(d).

REMARKS/ARGUMENTS

In the Office Action of October 22, 2004, the Examiner stated that the above-noted application includes claims directed to six individual "inventions" that "do not relate to a single inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features." Office Action, p. 2. Applicants assert that the six-way restriction made by the Examiner in the present case is improper under PCT rules 13.1 and 13.2. Further, the restriction is improper under the USPTO's own policies for the examination of national phase applications including nucleotide sequences. Each of these positions will be discussed in greater detail below.

The six-way restriction made by the Examiner in the present case is improper under PCT rules 13.1 and 13.2. More specifically, the Applicants submit that rule 13.2 may at best reasonably support a requirement to subdivide the claims of the present application into two distinct groups based upon the special technical features of the amino acid sequences of SEQ ID NOs: 2 and 4. Applicants believe that subdivision of the application into any more than two

groups, much less into six individual groups, violates the PCT rules governing unity of invention practice.

In the Office Action of October 22, 2004, the Examiner divided the claims of the present application into six groups and then attempted to identify the special technical features of each of the identified inventions. Group I is characterized by the Examiner as having a special technical feature of an isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 2, a vector and a host cell comprising the same. Group III's special technical feature is an isolated protein comprising the amino acid sequence of SEQ ID NO: 2. Group V is drawn to diagnostic methods using the spb1 gene product (this term is defined on page 4, lines 21-32 as being "a protein comprising the amino acid sequence of SEQ ID NO: 2).

On the other hand, Group II is characterized as having a special technical feature of an isolated nucleic acid molecule encoding the amino acid of SEQ ID NO: 4, a vector and a host cell comprising the same. Group IV has an isolated protein comprising the amino acid sequence of SEQ ID NO: 4, and Group VI is drawn to diagnostic methods using the spb2 gene product (defined in the specification, page 4, lines 23-25 as being "a protein comprising the amino acid sequence of SEQ ID NO: 4). Thus, groups I, III, and V identified by the Examiner share SEQ ID NO: 2 as a special technical feature, and groups II, IV, and VI identified by the Examiner share SEQ ID NO: 4 as a special technical feature. The Applicant believes that the application, if it may properly be divided at all, falls into at most two groups under PCT Rules 13.1 and 13.2: a first group including current groups I, III, and IV with the shared special technical feature of SEQ ID NO: 2; and a second group including current groups II, IV, and VI with the shared special technical feature of SEQ ID NO: 4 for reasons discussed in greater detail below.

PCT Rule 13.2 explains that the "unity of invention" requirement of PCT Rule 13.1 is fulfilled "when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." PCT Rule 13.2. The term "special technical features" is defined in this rule as being "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." *Id.* The present application presents two novel amino acid sequences that are each a contribution over the prior art. Specifically, the contributions made by the invention are

characterized by SEQ ID NOs: 2 and 4, corresponding to the *spb1* and *spb2* gene products, respectively.

Since the invention provides contributions in the form of SEQ ID NOs: 2 and 4, Rule 13.2 states that the unity of invention standard is met when "there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." PCT Rule 13.2. As briefly noted above, under this standard, groups I, III, and V should thus be examined together, since each is defined in terms of SEQ ID NO: 2: nucleic acid sequences encoding SEQ ID NO: 2, proteins including SEQ ID NO: 2, and diagnostic methods of detecting SEQ ID NO: 2. Similarly, groups II, IV, and VI should be examined together, since each is defined in terms of SEQ ID NO: 4: nucleic acid sequences encoding SEQ ID NO: 4, proteins including SEQ ID NO: 4, and diagnostic methods of detecting SEQ ID NO: 4. Since groups 1, III, and V and groups II, IV, and VI each include a shared special technical feature, it is violative of PCT rules 13.1 and 13.2 and overly restrictive to require election of only one of the currently defined "inventions" presented in groups I-VI.

In addition, the requirement made in the present case is contrary to current USPTO examination policy regarding restriction of applications that are United States nationalizations of PCT patent applications that include nucleotide sequences. *See, e.g.,* MPEP §803.04, 823, and §1850. Section 1850 of the MPEP states that "[t]he Commissioner has decided *sua sponte* to partially waive 37 CFR 1.475 and 1.499 *et seq.* to permit applicants to claim up to ten (10) nucleotide sequences that do not have the same or corresponding special technical feature without the payment of an additional fee." Later in the same section, the MPEP states that "claims directed to the selected sequences will be examined with claims drawn to any sequence combinations which have a common technical feature with the selected sequences. Nucleotide sequences encoding the same protein are considered to satisfy the unity of invention standard and will continue to be examined together." MPEP §1850. Thus, even if the Examiner believes that claims defined by different SEQ ID NOs should be restricted, the MPEP states that "up to ten (10) nucleotide sequences that do not have the same or corresponding special technical feature" are permitted in an application. The Requirement received in this case is thus inconsistent with

the procedures laid forth in the MPEP for addressing unity of invention issues in nationalized PCT cases.

Finally, MPEP §1850 provides additional breadth to nationalized PCT applications in which extra fees were paid during the international stage based on unity of invention. Specifically, §1850 provides that: "in international applications, for each group for which applicant has paid additional international search and/or preliminary examination fees, the USPTO has determined that up to four (4) such additional sequences per group is a reasonable number for examination." As noted on the Notification of Transmittal of the International Search Report received in the PCT case, form PCT/ISA/210, page 3, "all required additional search fees were timely paid by applicant." As a result, Applicant is entitled to additional sequences within the present application.

In addition to the above, the Applicants wish to express disappointment at the inequity of the six-way restriction requirement made in this Application. Specifically, restriction between nucleic acid sequences encoding an amino acid, an amino acid, and methods of detecting the amino acid as has been done herein places unfair and unexpected burdens on an Applicant in a case such as this. First, maintenance of such a restriction requirement could necessitate multiple duplicative patent filings based on an identical disclosure. This, in turn, results in redundant fee payments in order to assure complete protection of subject matter that is most properly subsumed within a single patent. Even if many of the remaining groups are abandoned, requiring election of one of the highly-related groups I, III, and V; or II, IV, and VI increases the costs of prosecution of the present application, further burdening the Applicants.

As a result, the Applicants respectfully request that this requirement be withdrawn in its entirety. Failing this, the Applicants request that the claims be re-grouped such that groups I, III, and V would be examined together; and groups II, IV, and VI would be examined together. Since this restriction/election requirement is improper under current law governing PCT patent filings, is inconsistent with existing USPTO policies, and is inequitable and burdensome to the Applicants, the Applicants respectfully request that it be immediately withdrawn, and that the originally-submitted claims be examined together in due course. The Applicants invite the

Examiner to contact the undersigned to discuss this matter. If the Examiner requires any further information he is requested to contact the undersigned.

Respectfully submitted,

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